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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,729	12/21/2001	Jaap M. Middeldorp	9250-13DVCTDV	6359

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EXAMINER
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KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/036,729

Applicant(s)

MIDDELDORP ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-9,23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9,23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/031,148.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z. 6) ☐ Other:

## DETAILED ACTION

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/031,148, filed on March 12, 1993.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 6-8 are drawn to a product of nature, i.e., a nucleic acid, and hence do not sufficiently distinguish any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447, U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventors, e.g., by insertion of "Isolated" or "Purified" as taught on page 21, Example 1, of the specification. See MPEP 2105.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6, 9, 23, and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 9, 23, 25, 28, and 29 are indefinite for the recitation of the phrase, "functional variant thereof," because it is unclear what nucleic acids are encompassed by this term and the specification does not describe what the phrase means, rendering the claims indefinite in their metes and bounds.

Claims 9, 26, and 27 are indefinite for the recitation of the term, "*recombinant* vector," because it is unclear what aspect of the vector makes the vector recombinant. Amending the claims to remove the term "*recombinant*" would overcome this rejection.

Claims 23, 28, and 29 are indefinite for lacking a proper antecedent basis. Claim 23 recites the phrase, "using at least one nucleic acid sequence or fragment thereof according to claim 6." However, claim 6 is not drawn to a fragment of a nucleic acid. Claims 28 and 29 are rejected under the same basis.

Claims 23, 28, and 29 are indefinite for failing to recite active method steps. Although the preambles recite the claims as being methods, no active steps are recited in the claims, rendering the claims indefinite in what steps are included or excluded in the method.

Claim 25 is indefinite because the claim only recites the intended use without reciting the actual ingredients in the kit, rendering the metes and bounds of the claim indefinite in what is included/excluded in/from the kit. For the purpose of prosecution, the claim is assumed to read on any amplification kit.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8, and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ambinder et al. (Abstracts from Annual Meeting American Society of Microbiology, 1989, 89 Meet., 111).

The instant rejection is predicated on the decision from *In re Mott*, 190 U.S.P.Q. 536 (CCPA 1975), wherein the court expressed that, “[c]laims must be given broadest reasonable construction their language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure.” As claims 7 and 8 are drawn to a nucleic acid comprising “at least a part of the nucleic acid sequence as shown in SEQ ID NO: 1.” Therefore, the claims, absent a specific definition set forth in the specification, based on a broadest reasonable interpretation (MPEP 904.01), will be interpreted as a nucleic acid sequence comprising a single common nucleotide to those of claimed SEQ ID Numbers. The rejection of claim 26-29 (the dependents thereto), is also under the same reasoning.

Ambinder et al. disclose a method of detecting EBV sequences in clinical specimen by amplification method involving primers (claims 28 and 29). A plasmid containing EBV is disclosed as being amplified, which evidences the presence of a nucleic acid encoding EBV with at least one common nucleotide with that of SEQ ID Number 1 or 3 (claims 7, 8, 26, and 27).

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In *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342 (CCPA 1968), the court expressed that, "in considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inference which one skilled in the art would reasonably be expected to draw therefrom."

Therefore, Ambinder et al. anticipate the invention as claimed.

### *Conclusion*

No claims are allowed.

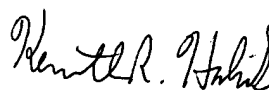
### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/5/03



  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

8/6/03